

### **REMARKS**

Upon entry of this paper, claims 1-18 are pending, in which claims 4, 9-16 and 18 are withdrawn. Claims 1 and 17 have been amended and claims 4, 9-16 and 18 which are withdrawn are currently amended to correct typographical errors. No new matter is added by the amendments made herein.

#### **The Claim Objection**

The Examiner has objected to claims 1 and 17 for informalities. Claims 1 and 17 have been amended to correct this and this objection should be considered moot. It is also noted that the spelling of “catechins” in claims 9 and 18 has also been corrected. Also, errors in claims 4, 10-16 and 18 have been corrected.

#### **The §112 Rejection**

The Examiner has rejected claims 1-3, 5-8 and 17 under 35 USC §112, second paragraph as allegedly being indefinite.

The Examiner alleges that the recitation of “...low metabolic rate” is indefinite. Applicants respectfully traverse this rejection.

Applicant respectfully submits that the artisan skilled in the art area of the present invention having the benefit of the present claims and supporting disclosure would be fully apprised of the scope and content of this claim term. Those skilled in the art of obesity treatment would readily recognize that control of a subject’s metabolic rate would influence weight gain or loss and that a low metabolic rate in a subject may be a factor in weight gain. The present claims which are directed to the treatment of obesity would clearly also encompass the treatment of a low metabolic rate.

For the above reasons, Applicant urges that this rejection is in error and applicants respectfully request reconsideration and withdrawal of the rejection.

#### **The §103(a) Rejections**

The Examiner has rejected claims 1, 3, 5-8 and 17 under 35 USC §103(a) as allegedly being unpatentable over U.S. Patent No. 6,610,749 to Liao, U.S. Patent No. 5,804,596 to Majeed, U.S. Patent No. 7,279,184 to Gow, U.S. Patent No. 6,251,888 to de la Harpe and BE 1009545.

The Examiner has also rejected claim 2 under 35 USC §103(a) as allegedly being unpatentable over U.S. Patent No. 6,610,749 to Liao, U.S. Patent No. 5,804,596 to Majeed, U.S. Patent No. 7,279,184 to Gow, U.S. Patent No. 6,251,888 to de la Harpe and BE 1009545 further in view of US 2003/0059403 to Chokshi.

In the Office Action, the Examiner states that:

“...applicant has not supported the assertion that these results are synergistic rather than additive (see MPEP section 716.02 (a)). An artisan of ordinary skill would clearly expect a combination of five weight loss ingredients to function in an increased manner in comparison with one weight loss ingredient. Thus, the showing that the combination of the five ingredients functions better than the single ingredient is not considered to be unexpected. In addition, the results shown in Figures 2A and 2B are not considered to be commensurate in scope with the claimed invention. This is because the results are only shown for one formulation that falls within the claimed percentages while the claims encompass numerous other embodiments that are not used to produce the experimental data (see MPEP section 716.02 (d)).”

With all due respect, Applicant urges that the Examiner has either not fully understood or has misinterpreted the data presented by Applicant in the present specification and explained in the response to the first Office Action.

Initially, Applicant notes that it has been acknowledged by the Examiner, that the references do not specifically teach adding the ingredients in the amounts claimed by Applicant. Clearly, there is no teaching that a combination of the various components of the presently claimed composition could be made with the expectation that the end result would be a composition which functions in a synergistic manner and hence provides an unexpected result.

As stated in MPEP § 2143.01, "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art." (Emphasis in original) (citing the KSR case) Applicant urges that the skilled artisan viewing the data provided in the instant specification would have concluded that the unique combination disclosed and claimed in the present application was an unexpected achievement. The Examiner should also note that the EPO has granted a patent to Applicant based

on the holding by the WIPO Examiner that the present application demonstrated an unexpected and synergistic combination.

Figs. 2A and 2B, of the present application show that the individual constituents green tea extract, *coleus forskohlii*, Yerba Mate, and *Betula Alba* each individually provides substantially the same effect as the other individual constituents on body weight increase and on the mean rate of change of body weight of tested rats. In Fig. 2A there is shown that the increase in body weights of the tested rats that were fed only individual constituents of the claimed invention, and at the end of 12 weeks the effect of each individual constituent was within the narrow range of from about 42% to about 46%, whereas the corresponding increase for the claimed composition was significantly lower at about 32%. One of only ordinary skill in the art would conclude that a combination of the individual components would provide a result which would be about the same as the individual component results, i.e., a range of between 42 to about 46% rather than an almost 30% enhanced result for the combination of the present invention.

Fig. 2B shows the mean change in body weights of the tested rats fed only individual constituents of the claimed invention, and at the end of 3 months each change was within the narrow range of from about 71% to about 79%, whereas the change over that same time interval for the claimed composition was significantly lower at 60%. Again, the artisan would not have expected a much better result for the combination whereas the combination actually gave an about 30% enhanced effect.

Applicant urges that present application provides ample evidence of the synergistic effect of the claimed invention, i.e., an about 30% enhanced result, by virtue of the examples and the tables that are included in the specification along with Figs. 2A and 2B of the drawings.

Applicant further urges that Applicant has provided further data to demonstrate the unobviousness of the presently claimed combination. Figure 1 shows a comparison of the present combination against Xenical with respect to lipase activity. Xenical is a known treatment for obesity which acts via lipase inhibition. The present combination provides significant inhibition without the negative side effects of Xenical. It would have been clear to the artisan from Fig. 3 that the mean food intake in the tested rats is lowest in the group treated with the formulation of the invention and that this effect is sufficiently significant to conclude that synergism was achieved by the invention

formulation.

The Examiner also contends that the unexpected result shown by Applicant is not commensurate with the scope of the claims. Applicant urges that the Examiner has not provided any basis for this allegation. As can be seen from the results of Figs. 2A and 2B the individual components provided an approximately equivalent result with respect to the tests in these studies. The artisan would have expected similar results for all of the possible ranges of the individual components. Similarly, the artisan knowing that the combination provided an enhanced and unexpected effect for the concentrations shown in the tests of Figs. 2A and 2B would have expected similar enhanced and unexpected effects throughout the entire range recited in the instant claims. Applicant also points out that the Examiner has simply concluded that the data provided by Applicant does not demonstrate an unexpected result. No evidentiary basis is given by the Examiner that substantiates this position. Applicant urges that sufficient data and reasoning has been presented to allow a conclusion that the present combination formulation provides an unexpected result.

For the above reasons, Applicant requests reconsideration by the Examiner and urges that the Examiner withdraw the rejection of the present claims. Should the Examiner have any questions or comments regarding this matter, the undersigned may be contacted at the below-listed telephone number.

Respectfully submitted,  
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